

**2SHB 3181** - H AMD TO H AMD (H-5640.1/10) **1588**

By Representative Morrell

On page 2, line 7 of the amendment, after "(a)" insert "(i)"

On page 2, after line 10 of the amendment, insert the following:

"(ii) A tax is imposed on the privilege of manufacturing drugs for distribution in the state of Washington. The rate of the tax is seven-tenths of one percent multiplied by the wholesale value of the manufactured drug. This tax does not apply to drug manufacturers who participate in a product stewardship program for unwanted drugs from residential sources under section 7 of this act."

On page 5, after line 30 of the amendment, insert the following:

"NEW SECTION. Sec. 7. (1) Beginning January 1, 2012, every producer of drugs sold in or into Washington state must participate in a product stewardship program for unwanted drugs from residential sources.

(2) Every producer must:

(a) Operate, either individually or jointly with other producers, a product stewardship program; or

(b) Enter into an agreement with a stewardship organization to operate, on the producer's behalf, a product stewardship program.

(3) A product stewardship program must be licensed by the board of pharmacy prior to collecting unwanted drugs from residential sources.

(4) A producer, group of producers, or stewardship organization must pay all administrative and operational costs associated with their product stewardship program, including the cost of the collection, transportation, and disposal of the unwanted products that are collected from residential sources and the recycling or disposal, or both, of its related packaging that is collected with the unwanted drugs.

1 (5) A product stewardship program must be provided without charging  
2 any fee at the time of sale of the drug or at the time the unwanted  
3 drugs from residential sources are delivered or collected for disposal.

4 (6) Unless otherwise approved by the board of pharmacy, each  
5 product stewardship program must accept all unwanted drugs regardless  
6 of who produces the unwanted drug.

7 (7) A producer, group of producers, or stewardship organization  
8 operating or intending to operate a product stewardship program must  
9 submit a product stewardship plan to the board of pharmacy prior to  
10 engaging in the collection of unwanted covered drugs.

11 **Sec. 8.** RCW 82.21.020 and 2002 c 105 s 1 are each amended to read  
12 as follows:

13 Unless the context clearly requires otherwise, the definitions in  
14 this section apply throughout this chapter.

15 (1) "Drugs" means (a) articles recognized in the official United  
16 States pharmacopoeia, the official national formulary, the official  
17 homeopathic pharmacopoeia of the United States, or any supplement of  
18 the formulary or those pharmacopoeias; (b) substances intended for use  
19 in the diagnosis, cure, mitigation, treatment, or prevention of disease  
20 in humans or other animals; (c) substances, other than food, intended  
21 to affect the structure or any function of the body of humans or other  
22 animals; or (d) substances intended for use as a component of any  
23 substances specified in (a), (b), or (c) of this subsection, but not  
24 including medical devices or their component parts or accessories.

25 (2) "Hazardous substance" means:

26 (a) Any substance that, on March 1, 2002, is a hazardous substance  
27 under section 101(14) of the federal comprehensive environmental  
28 response, compensation, and liability act of 1980, 42 U.S.C. Sec.  
29 9601(14), as amended by Public Law 99-499 on October 17, 1986, except  
30 that hazardous substance does not include the following noncompound  
31 metals when in solid form in a particle larger than one hundred  
32 micrometers (0.004 inches) in diameter: Antimony, arsenic, beryllium,  
33 cadmium, chromium, copper, lead, nickel, selenium, silver, thallium, or  
34 zinc;

35 (b) Petroleum products;

36 (c) Any pesticide product required to be registered under section

1 136a of the federal insecticide, fungicide and rodenticide act, 7  
2 U.S.C. Sec. 136 et seq., as amended by Public Law 104-170 on August 3,  
3 1996; and

4 (d) Any other substance, category of substance, and any product or  
5 category of product determined by the director of ecology by rule to  
6 present a threat to human health or the environment if released into  
7 the environment. The director of ecology (~~((shall))~~) may not add or  
8 delete substances from this definition more often than twice during  
9 each calendar year. For tax purposes, changes in this definition  
10 (~~((shall))~~) take effect on the first day of the next month that is at  
11 least thirty days after the effective date of the rule. The word  
12 "product" or "products" as used in this paragraph (d) means an item or  
13 items containing both: (i) One or more substances that are hazardous  
14 substances under (a), (b), or (c) of this subsection or that are  
15 substances or categories of substances determined under this paragraph  
16 (d) to present a threat to human health or the environment if released  
17 into the environment; and (ii) one or more substances that are not  
18 hazardous substances.

19 (~~((+2))~~) (3) "Petroleum product" means plant condensate, lubricating  
20 oil, gasoline, aviation fuel, kerosene, diesel motor fuel, benzol, fuel  
21 oil, residual oil, liquefied or liquefiable gases such as butane,  
22 ethane, and propane, and every other product derived from the refining  
23 of crude oil, but the term does not include crude oil.

24 (~~((+3))~~) (4) "Possession" means the control of a hazardous substance  
25 located within this state and includes both actual and constructive  
26 possession. "Actual possession" occurs when the person with control  
27 has physical possession. "Constructive possession" occurs when the  
28 person with control does not have physical possession. "Control" means  
29 the power to sell or use a hazardous substance or to authorize the sale  
30 or use by another.

31 (~~((+4))~~) (5) "Previously taxed hazardous substance" means a  
32 hazardous substance in respect to which a tax has been paid under this  
33 chapter and which has not been remanufactured or reprocessed in any  
34 manner (other than mere repackaging or recycling for beneficial reuse)  
35 since the tax was paid.

36 (~~((+5))~~) (6) "Producer" means the person who:

37 (a) Has legal ownership of the brand, brand name, or co-brand of  
38 the drug or manufactures a generic drug sold in or into Washington

1 state. "Producer" does not include a retailer who puts its store label  
2 on a drug or a pharmacist who compounds a prescribed individual drug  
3 product for a patient;

4 (b) Imports a drug branded or manufactured by a producer that meets  
5 the definition under (a) of this subsection and where that producer has  
6 no physical presence in the United States; or

7 (c) Sells at wholesale a drug, does not have legal ownership of the  
8 brand, and elects to fulfill the responsibilities of the producer for  
9 that product.

10 (7) "Wholesale value" means fair market wholesale value, determined  
11 as nearly as possible according to the wholesale selling price at the  
12 place of use of similar substances of like quality and character, in  
13 accordance with rules of the department.

14 ((+6+)) (8) Except for terms defined in this section, the  
15 definitions in chapters 82.04, 82.08, and 82.12 RCW apply to this  
16 chapter.

17 NEW SECTION. Sec. 9. Section 7 of this act constitutes a new  
18 chapter in Title 70 RCW."

19 Renumber the remaining sections consecutively and correct any  
20 internal references accordingly.

EFFECT: Requires drug manufacturers whose drugs are distributed in Washington State to pay a drug manufacturing tax on the wholesale value of the drugs manufactured unless they participate in a product stewardship program licensed by the Board of Pharmacy for unwanted drugs from residential sources. (The tax rate would be 0.7 percent, which is equivalent to the current hazardous substance tax rate.)

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